PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 20 November 2000 (20.11.00)	
International application No. PCT/SE00/00615	**Applicant's or agent's file reference** GA 280 PCT
International filing date (day/month/year) 30 March 2000 (30.03.00)	**Priority date** (day/month/year) 30 March 1999 (30.03.99)
Applicant JANSSON, Olof et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

18 October 2000 (18.10.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer A. Karkachi
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

SPITMANN, Knut, H.
Gambro Lundia AB
P.O. Box 10101
S-220 10 Lund
SUÈDE

Date of mailing (day/month/year)
20 November 2000 (20.11.00)

Applicant's or agent's file reference
GA 280 PCT

IMPORTANT NOTIFICATION

International application No.
PCT/SE00/00615

International filing date (day/month/year)
30 March 2000 (30.03.00)

1. The following indications appeared on record concerning:

[ ] the applicant [ ] the inventor [X] the agent [ ] the common representative

Name and Address
GAMBRO LUNDIA AB
Asketorp, Göran
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S-220 10 Lund
Sweden

State of Nationality:
State of Residence:
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Facsimile No.: +46/46-16-91-89
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[X] the person [ ] the name [ ] the address [ ] the nationality [ ] the residence

Name and Address
SPITMANN, Knut, H.
Gambro Lundia AB
P.O. Box 10101
S-220 10 Lund
Sweden

State of Nationality:
State of Residence:
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Facsimile No.: +46/46-16-91-89
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer
A. Karkachi

Telephone No.: (41-22) 338.83.38

Form PCT/IB/306 (March 1994)

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

Applicant's or agent's file reference GA 280 PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/SE00/00615	International filing date *(day month year)* 30.03.2000	Priority date *(day month year)* 30.03.1999
International Patent Classification (IPC) or national classification and IPC7 A61M 1/28, 1/14; A61J 1/06, 3/00; B01D 61/26, 61/28, 61/32		
Applicant Gambro Lundia AB et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 16 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
18.10.2000	19.06.2001
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88 Telex 17978 PATOREG-S	Authorized officer Frida Plym Forshell /OGU Telephone No. 08-782 25 00

Form PCT/IPEA/409 (cover sheet) (January 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/SE00/00615

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed

pages _____, as amended (together with any statement) under article 19

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheet/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2 (c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/SE00/00615

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. see Supplemental Box

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____
are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. see Supplemental Box

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box III.

claims Nos.

5,15,17-45,103-106,123-131,141-143

no international search report has been established for said claims Nos.

5,15,17-45,103-106,123-131,141-143

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

   ☐ restricted the claims.

   ☒ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features.

A priori, claims 1-4, 6-14, 16, 46-102, 107-122 and 132-140 comprise four inventions not fulfilling the requirements for unity of invention, namely:

I. A container with a plurality of chambers according to claims 1-4, 6-14 and 16.

II. A method of making a dialysis solution using a plurality of compartments according to claims 46-76, 100-102 and 107-122.

III. A method of making an aqueous solution for medical use according to claims 77-99.

IV. A processor for dialysis prescription information according to claims 132-140.

Since no common or corresponding feature exists which can be considered as a special technical feature within the meaning of PCT Rule 13.2, second sentence, no technical relationship, within the meaning of PCT Rule 13, can be identified between these different inventions. .../...

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-4,6-14,16,46-102,107-122,132-140

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box IV., 3.

WO 9508299 discloses a container comprising a plurality of chambers containing concentrates of peritoneal dialysis fluid. Therefore, the container according to claim 1 lacks novelty.

Since the invention (I) defined in claim 1 is not novel claims 1-4, 6-14 and 16 form two inventions as follows:

1. A container according to claims 1-4 and 6-7.
2. A container according to claims 8-14 and 16.

The inventions share in common the technical features defined in claim 1. Since the invention defined in claim 1 is not novel, no common or corresponding feature exists which can be considered as a special technical feature within the meaning of PCT Rule 13.2, second sentence. Accordingly, no technical relationship, within the meaning of PCT Rule 13, can be identified between the different inventions.

Therefore, à posteriori, claims 1-4, 6-14, 16, 46-102, 107-122 and 132-140 comprise five inventions not fulfilling the requirements of unity of invention.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	see Supplemental Box	YES
	Claims	see Supplemental Box	NO
Inventive step (IS)	Claims	see Supplemental Box	YES
	Claims	see Supplemental Box	NO
Industrial applicability (IA)	Claims	see Supplemental Box	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Inventions

Invention 1: Claims 1-4 and 6-7.
The claimed invention relates to a container used with an apparatus for producing peritoneal dialysis fluid. The container comprises chambers with concentrates of dialysis fluid. Some concentrates are provided in dry form. The invention improves packaging and transport of the constituents of the dialysis fluid and also increases shelf life and decreases precipitation problems.

Invention 2: Claims 8-14 and 16.
The claimed invention relates to a container with a plurality of chambers equipped with connectors comprising at least two fluid channels. The two channels allow simultaneous flow in two directions.

Invention 3: Claims 46-76, 100-102 and 107-122.
The claimed invention relates to a method, a system and an apparatus for dialysis solution preparation using a plurality of chambers containing concentrates of dialysis fluid. The invention is intended for preparation of dialysis fluid at a patient treatment site by mixing the concentrates with water.

Invention 4: Claims 77-99.
The claimed invention reveals a method of making an aqueous solution for medical use from a plurality of concentrates.

Invention 5: Claims 132-140.
The claimed invention reveals a processor for dialysis prescriptions used for patient-specific production of dialysis fluid. With the processor, preparation of different dialysis fluids for different patients or different occasions is possible.

.../...

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V., 1.

Novelty (N)	Claims	2-4,6-14,16,46-67,69,74,79-84,86-88,91-96, 98-100,107-122,132-140	YES
	Claims	1,68,70-73,75-78,85,89-90,97,101-102	NO
Inventive Step (IS)	Claims	113-119	YES
	Claims	1-4,6-14,16,46-102,107-112,120-122,132-140	NO
Industrial applicability (IA)	Claims	1-4,6-14,16,46-102,107-122,132-140	YES
	Claims		NO

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V., 2.

Prior art

D1: WO 95/08299 A1
D2: US 4661246 A
D3: US 4608043 A
D4: EP 0714668 A1
D5: JP 08164198 A
D6: WO 98/32478 A1
D7: DE 3844174 A1
D8: US 5318750 A
D9: EP 0428009 A1
D10: EP 0458041 A1
D11: EP 0443324 A1
D12: DE 4419567 A1
D13: EP 0278100 A2
D14: DE 29814561 U1
D15: US 5643201 A
D16: US 5304130 A
D17: US 4573967 A
D18: US 5074844 A

D1 describes a liquid mixing assembly for peritoneal dialysis. The assembly comprises a container with at least two separate compartments containing different liquids subsequently mixed to form the dialysis solution (see page 2, line 33-page 3, line 1; figure 1 and the abstract.)

D2 discloses a dialysis instrument with a removable and disposable cartridge. The cartridge comprises containers with different components for the dialysis fluid, e.g., dry salts. Dialysis solution is mixed from the different components during a priming procedure. Among the containers in the cartridge are a calcium chloride container and a potassium/hydrogen citrate reservoir. A prime/flush solution is used to rinse tubes in the cartridge before and after use (see column 2, line 33-line 42; column 10, line 58-column 11, line 6 and figures 1 and 2.)

In D3, a container for separate storage and sterile mixing of the contents in different chambers is described. The contents may comprise a liquid diluent, such as water or a saline solution, and a powdered or liquid medicament (see column 1, line 5-line 17 and figure 1.)

D4 reveals a method and an arrangement for preparation of dialysis solution from a saturated salt concentrate. Water is

.../...

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V., 2.

supplied to excess amounts of salt in particle form and the salt is continuously dissolved until the water becomes saturated. The conduits in the container can be disinfected with heated salt concentrate (see column 5, line 25-line 38 and the abstract.)

D5 describes a container with multiple chambers containing solid components of dialysis solution. The components include sodium bicarbonate, sodium chloride and glucose (see figure 1 and the abstract.)

D6 shows an example of a solution delivery system that can be used for continuous ambulatory peritoneal dialysis. The system comprises administration lines with double inner lumens that permit simultaneous inflow and outflow. The lines can be placed in the lower region of a compartment holding the solution to be distributed, and one lumen can be arranged to extend higher into the compartment than the other lumen. Concentrical lumens are possible (see page 2, line 32-page 3, line 15 and figures 1-5.)

In D7, a system for production of dialysis solution is described. Solid and liquid components are mixed in a mixing chamber. Liquid can be introduced in the mixing chamber through a diffuser (see claim 8 and figure 1.)

D8 reveals a device for preparation of dialysis fluid by dissolution of substances in powder form. The device comprises a number of cells containing concentrates of the dialysis fluid, conduits that distribute purified water to the cells in order to make aqueous solutions of the components and a mixing point where the different solutions are mixed. Measurement means and regulation means co-operate to control the concentrations of the different aqueous solutions. The device can adapt the composition of the dialysate to each patient as a function of patient-specific data. The cells can be grouped in a single housing, and may contain sodium chloride or glucose (see column 1, line 60-column 2, line 15; column 3, line 11-line 16; column 4, line 25-line 32 and figure 1.)

D9 describes a method for preparation of sterile dialysis fluid. Water is continually transported from a source to a point of consumption and necessary concentrates in liquid or powdered form are added during the transport. For sterilisation, the dialysis fluid is heated during a certain time and then cooled to consuming temperature. A venting point

.../...

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V., 2.

is included in the system to remove air liberated during the heating (column 2, line 52-column 3, line 3 and column 6, line 27-line 31.)

In D10, a system for controlling dialysis treatment is described. The system includes a cartridge with a soluble concentrate which, after being dissolved, is used to clean the system (see column 2, line 1-line 13.)

D11 discloses a system for preparation of dialysis fluid. The system includes a source of pure water, at least one cartridge with powder to be dissolved for preparation of the fluid and means for conducting the water to the cartridge. A mixing vessel and a re-circulation circuit are used to re-circulate the water through the cartridge until an appropriate fluid concentration is obtained by dissolving the powder in the cartridge partly or entirely (see column 1, line 40-line 58.)

D12 reveals a method and a system for automatic mixing of liquid chemicals following a prescription. The system includes a mixing station with two pumps, valves and sensors used to regulate the mixing of the used chemicals. One pump is used to pump the different chemicals to the mixing station and the other pump is used to pump water. A computer is used to execute the mixing of chemicals following a prescription (see column 1, line 29-line 47; column 2, line 46-line 62; column 4, line 1-line 7 and line 27-line 56 and figures 1 and 2.)

In D13, a system for preparing a medical fluid by mixing concentrates in powder form with water is described. In this system, some powder is dissolved when water is introduced in the powder cartridge. After leaving the cartridge, the liquid solution is diluted to proper concentration by mixing with more water. Different pumps control the flow of liquid from the water reservoir and the powder cartridges. For disinfection, liquid is passed through the system by reversing pumping direction (see page 4, line 18-line 32; page 9, line 24-line 42; the abstract and figure 8.)

D14 describes a water purifier with two reverse osmosis membrane units coupled in series (see claim 1.)

D15 discloses a continuous peritoneal dialysis system in which dialysis fluid is continuously produced (see the abstract and claim 1.)

.../...

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V., 2.

D16 reveals a container for controlled administration of its contents. The container is equipped with a connector with two channels. One channel extends to an upper region of the container (see column 2, line 47-line 60 and figure 2).

D17 describes a penetrating spike with two pathways permitting simultaneous inflow to and outflow from a vial connected to an intravenous administration set (see the abstract and figure 2).

In D18, a drug delivery system is revealed. The system is equipped with a connector with two spikes permitting simultaneous inflow to and outflow from a cartridge containing the drug. One spike extends to the upper portion of the cartridge (see figure 9).

Statement of reasons
Invention 1

The closest prior art is the liquid mixing assembly for peritoneal dialysis disclosed in D1. It reveals the present invention described in claim 1. This claim is therefore not novel.

Using concentrates in powder form, among these glucose and inorganic salts, is well known in the art, see D3, D4 or D5 for example. It is considered obvious for a person skilled in the art to include dry concentrates, sometimes enough to make saturated solutions, in the container according to claim 1. Therefore, claims 2-4 are not considered to involve an inventive step.

The cartridge for production of dialysis fluid described in D2 and the system for controlling a dialysis treatment disclosed in D10 include cleaning solutions. It is considered obvious for a person skilled in the art, even without further knowledge of D2 or D10, to include a chamber with a cleaning agent in the container disclosed in D1, thereby arriving at the invention according to claim 6. What is claimed in claim 7 is also considered obvious for the person skilled in the art, since preparing solutions with different conductivities is well known and often used in dialysis fluid preparation. Thus, claims 6 and 7 are not considered to involve an inventive step.

Accordingly, claim 1 is not novel. Claims 2-4 and 6-7 are novel but not considered to involve an inventive step. The invention fulfils the requirement of industrial applicability.

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Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V., 2.

Invention 2

The closest prior art is the liquid mixing assembly for peritoneal dialysis disclosed in D1. The difference between this assembly and the invention according to claim 8 is the special connectors with double lumens, with which the chambers of the invention are equipped. Double lumen connectors permitting simultaneous flow in two directions in production and supply of peritoneal dialysis solution are known through D6. It is considered obvious for a person skilled in the art to apply the connector technique disclosed in D6 on the assembly for liquid mixing in D1 to allow simultaneous inflow and outflow from the different chambers, thereby arriving at the invention according to claims 8, 9 and 11. These claims are therefore not considered to involve an inventive step.

A diffuser that diffuses inflow of liquid in a mixing chamber for dialysis solution is known through D7. Hence, it is considered obvious for a person skilled in the art to provide a diffuser on a fluid channel for inflow into a chamber in the assembly described in D1. The contents of claim 12 are therefore not considered to involve an inventive step.

To add an extra connector with one channel only or to align the connectors along a linear axis, central or not, is considered as obvious constructional details for the person skilled in the art. Thus, claims 10, 13, 14 and 16 are not considered to involve an inventive step.

Accordingly, claims 8-14 and 16 are novel but not considered to involve an inventive step. The requirement of industrial applicability is fulfilled.

Invention 3

The closest prior art is the device for preparation of dialysis fluid described in D8. It reveals the present invention described in claims 68, 70-73, 75-76 and 101-102. These claims are therefore not novel.

The device disclosed in D8 differs from the present invention as described in claims 46-67, 69, 74, 100, and 107-122. For example, it does not contain a steriliser, a heater and a vent. However, it is considered obvious for a person skilled in the art to modify the system in D8 with these details since they represent known components in dialysis fluid production systems, for example the one described in D9. Thereby, the person skilled in the art arrives at the invention as described in claims 46-51, 56-67 and 74 and these claims are

.../...

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V., 2. 6(7)

therefore not considered to involve an inventive step.
To produce peritoneal dialysis fluid chosen from a group of formulations, the invention includes a controller that controls the mixing as described in claims 53-55 and 107-112. Using a controller and a processor, both included in a computer, for mixing of chemicals following a prescription is known through D12. It is considered obvious for the person skilled in the art to equip the system described in D8 with a controller to be able to make different dialysis fluids for different patients since this is one of the intentions with the system (see especially column 3, line 11-line 16 of D8.) Thus, claims 53-55 and 107-112 are not considered to involve an inventive step.
To include a cell with cleaning agent, to provide a diffuser in a cell with glucose, or to include a water purifier in the system are considered obvious constructional details for the person skilled in the art. These details are known in dialysis systems, see D7, D10 and D14. Claims 52, 69 and 120-122 are therefore not considered to involve an inventive step.
Flushing the liquid path by reversing a pump as described in claim 100 is known through D13. Hence, claim 100 is not considered to involve an inventive step.

Accordingly, claims 68, 70-73, 75-76 and 101-102 are not novel. Claims 46-67, 69, 74, 100, 107-112 and 120-122 are novel but not considered to involve an inventive step. However, claims 113-119 are novel and considered to involve an inventive step. All claims fulfil the requirement of industrial applicability.

Invention 4
The closest prior art is the device for preparation of dialysis fluid described in D8. It reveals the present invention described in claims 77-78, 85, 89-90 and 97. These claims are therefore not novel.

The invention of claims 79-83, 86-88, 91-95 and 98-99 uses a single pump for distribution of the concentrates and the concentrates are diluted after leaving their chambers. This differs from the device disclosed in D8. Also, in the invention the pump is reversed to flush a part of the liquid path. However, the one-pump system is known through D12. Diluting the concentrates, controlling a pump to obtain a desired fluid concentration in a system for preparation of medical fluids and reversing a pump to flush a liquid path is described in D13. It is considered obvious for a person

.../...

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

skilled in the art and with prior knowledge of D12 and D13 to modify the device described in D8 with these details, thereby arriving at the invention according to claims 79-83, 86-88, 91-95 and 98-99. These claims are therefore not considered to involve an inventive step.
In claims 84 and 96 calculations of the total amount of concentrate material delivered to a mixing vessel are included. However, using a processor to calculate different characteristics based on sensed parameter values in a system for mixing of different liquids is known through D12. Therefore, it is considered obvious for a person skilled in the art to include these details in the system described in D8 and claims 84 and 96 are not considered to involve an inventive step.

Accordingly, claims 77-78, 85, 89-90 and 97 are not novel. Claims 79-84, 86-88, 91-96 and 98-99 are novel but not considered to involve an inventive step. The requirement of industrial applicability is fulfilled.

Invention 5
Systems for continuous peritoneal dialysis in which dialysis fluid is continuously produced are well known in the art, see D15. The device for preparation of dialysis fluid described in D8 can be used for peritoneal dialysis production and represents the closest prior art. It differs from the invention since it does not provide a processor, a controller, a portable memory and a data input interface. In the system for automatic mixing of liquid chemicals described in D12, a computer with a processor, a memory and an input interface is used to execute the mixing following a prescription. It is considered obvious for a person skilled in the art, with prior knowledge of D12, to computerise the system in D8 to be able to produce different solutions after user input. Thereby he arrives at the invention described in claims 132-140 and these claims are therefore not considered to involve an inventive step.

Accordingly, claims 132-140 are novel and fulfil the requirement of industrial applicability but are not considered to involve an inventive step.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The connection of claim 100 to any of claims 48 to 58 seems erroneous. The pump referred to in the claim can not be found in any of these claims.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

ANKOM
2001 -07- 0 3

Gambro Lundia AB
Patent Department
P.O. Box 10101
220 10 LUND

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	29-06-2001

Applicant's or agent's file reference	IMPORTANT NOTIFICATION
GA 280 PCT	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/SE00/00615	30-03-2000	30-03-1999

Applicant
Gambro Lundia AB
et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in som Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary axamination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88 Telex 17978 PATOREG-S	Carolina Holmberg Telephone No. 08-782 25 00

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
GA 280 PCT		
International application No.	International filing date *(day month year)*	Priority date *(day/month/year)*
PCT/SE00/00615	30.03.2000	30.03.1999
International Patent Classification (IPC) or national classification and IPC7		
A61M 1/28, 1/14; A61J 1/06, 3/00; B01D 61/26, 61/28, 61/32		
Applicant		
Gambro Lundia AB et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 16 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
18.10.2000	19.06.2001
Name and mailing address of the IPEA/SE	Authorized officer
Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88	Telex 17970 PATOREG-S Frida Plym Forshell /OGU Telephone No. 08-782 25 00

Form PCT/IPEA/409 (cover sheet) (January 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/SE00/00615

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement) under article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheet/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2 (c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/SE00/00615

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. see Supplemental Box

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____
are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. see Supplemental Box

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box III.

claims Nos.

5,15,17-45,103-106,123-131,141-143

no international search report has been established for said claims Nos.

5,15,17-45,103-106,123-131,141-143

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☒ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:

Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features.

A priori, claims 1-4, 6-14, 16, 46-102, 107-122 and 132-140 comprise four inventions not fulfilling the requirements for unity of invention, namely:

I. A container with a plurality of chambers according to claims 1-4, 6-14 and 16.

II. A method of making a dialysis solution using a plurality of compartments according to claims 46-76, 100-102 and 107-122.

III. A method of making an aqueous solution for medical use according to claims 77-99.

IV. A processor for dialysis prescription information according to claims 132-140.

Since no common or corresponding feature exists which can be considered as a special technical feature within the meaning of PCT Rule 13.2, second sentence, no technical relationship, within the meaning of PCT Rule 13, can be identified between these different inventions. .../...

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1-4,6-14,16,46-102,107-122,132-140

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box IV., 3.

WO 9508299 discloses a container comprising a plurality of chambers containing concentrates of peritoneal dialysis fluid. Therefore, the container according to claim 1 lacks novelty.

Since the invention (I) defined in claim 1 is not novel claims 1-4, 6-14 and 16 form two inventions as follows:

1. A container according to claims 1-4 and 6-7.
2. A container according to claims 8-14 and 16.

The inventions share in common the technical features defined in claim 1. Since the invention defined in claim 1 is not novel, no common or corresponding feature exists which can be considered as a special technical feature within the meaning of PCT Rule 13.2, second sentence. Accordingly, no technical relationship, within the meaning of PCT Rule 13, can be identified between the different inventions.

Therefore, à posteriori, claims 1-4, 6-14, 16, 46-102, 107-122 and 132-140 comprise five inventions not fulfilling the requirements of unity of invention.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	see Supplemental Box	YES
	Claims	see Supplemental Box	NO
Inventive step (IS)	Claims	see Supplemental Box	YES
	Claims	see Supplemental Box	NO
Industrial applicability (IA)	Claims	see Supplemental Box	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Inventions

Invention 1: Claims 1-4 and 6-7.
The claimed invention relates to a container used with an apparatus for producing peritoneal dialysis fluid. The container comprises chambers with concentrates of dialysis fluid. Some concentrates are provided in dry form. The invention improves packaging and transport of the constituents of the dialysis fluid and also increases shelf life and decreases precipitation problems.

Invention 2: Claims 8-14 and 16.
The claimed invention relates to a container with a plurality of chambers equipped with connectors comprising at least two fluid channels. The two channels allow simultaneous flow in two directions.

Invention 3: Claims 46-76, 100-102 and 107-122.
The claimed invention relates to a method, a system and an apparatus for dialysis solution preparation using a plurality of chambers containing concentrates of dialysis fluid. The invention is intended for preparation of dialysis fluid at a patient treatment site by mixing the concentrates with water.

Invention 4: Claims 77-99.
The claimed invention reveals a method of making an aqueous solution for medical use from a plurality of concentrates.

Invention 5: Claims 132-140.
The claimed invention reveals a processor for dialysis prescriptions used for patient-specific production of dialysis fluid. With the processor, preparation of different dialysis fluids for different patients or different occasions is possible.

.../...

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V., 1.

Novelty (N)	Claims	2-4,6-14,16,46-67,69,74,79-84,86-88,91-96, 98-100,107-122,132-140	YES
	Claims	1,68,70-73,75-78,85,89-90,97,101-102	NO
Inventive Step (IS)	Claims	113-119	YES
	Claims	1-4,6-14,16,46-102,107-112,120-122,132-140	NO
Industrial applicability (IA)	Claims	1-4,6-14,16,46-102,107-122,132-140	YES
	Claims		NO

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V., 2.

Prior art
D1: WO 95/08299 A1
D2: US 4661246 A
D3: US 4608043 A
D4: EP 0714668 A1
D5: JP 08164198 A
D6: WO 98/32478 A1
D7: DE 3844174 A1
D8: US 5318750 A
D9: EP 0428009 A1
D10: EP 0458041 A1
D11: EP 0443324 A1
D12: DE 4419567 A1
D13: EP 0278100 A2
D14: DE 29814561 U1
D15: US 5643201 A
D16: US 5304130 A
D17: US 4573967 A
D18: US 5074844 A

D1 describes a liquid mixing assembly for peritoneal dialysis. The assembly comprises a container with at least two separate compartments containing different liquids subsequently mixed to form the dialysis solution (see page 2, line 33-page 3, line 1; figure 1 and the abstract.)

D2 discloses a dialysis instrument with a removable and disposable cartridge. The cartridge comprises containers with different components for the dialysis fluid, e.g., dry salts. Dialysis solution is mixed from the different components during a priming procedure. Among the containers in the cartridge are a calcium chloride container and a potassium/hydrogen citrate reservoir. A prime/flush solution is used to rinse tubes in the cartridge before and after use (see column 2, line 33-line 42; column 10, line 58-column 11, line 6 and figures 1 and 2.)

In D3, a container for separate storage and sterile mixing of the contents in different chambers is described. The contents may comprise a liquid diluent, such as water or a saline solution, and a powdered or liquid medicament (see column 1, line 5-line 17 and figure 1.)

D4 reveals a method and an arrangement for preparation of dialysis solution from a saturated salt concentrate. Water is

.../...

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V., 2.

supplied to excess amounts of salt in particle form and the salt is continuously dissolved until the water becomes saturated. The conduits in the container can be disinfected with heated salt concentrate (see column 5, line 25-line 38 and the abstract.)

D5 describes a container with multiple chambers containing solid components of dialysis solution. The components include sodium bicarbonate, sodium chloride and glucose (see figure 1 and the abstract.)

D6 shows an example of a solution delivery system that can be used for continuous ambulatory peritoneal dialysis. The system comprises administration lines with double inner lumens that permit simultaneous inflow and outflow. The lines can be placed in the lower region of a compartment holding the solution to be distributed, and one lumen can be arranged to extend higher into the compartment than the other lumen. Concentrical lumens are possible (see page 2, line 32-page 3, line 15 and figures 1-5.)

In D7, a system for production of dialysis solution is described. Solid and liquid components are mixed in a mixing chamber. Liquid can be introduced in the mixing chamber through a diffuser (see claim 8 and figure 1.)

D8 reveals a device for preparation of dialysis fluid by dissolution of substances in powder form. The device comprises a number of cells containing concentrates of the dialysis fluid, conduits that distribute purified water to the cells in order to make aqueous solutions of the components and a mixing point where the different solutions are mixed. Measurement means and regulation means co-operate to control the concentrations of the different aqueous solutions. The device can adapt the composition of the dialysate to each patient as a function of patient-specific data. The cells can be grouped in a single housing, and may contain sodium chloride or glucose (see column 1, line 60-column 2, line 15; column 3, line 11-line 16; column 4, line 25-line 32 and figure 1.)

D9 describes a method for preparation of sterile dialysis fluid. Water is continually transported from a source to a point of consumption and necessary concentrates in liquid or powdered form are added during the transport. For sterilisation, the dialysis fluid is heated during a certain time and then cooled to consuming temperature. A venting point

.../...

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

is included in the system to remove air liberated during the heating (column 2, line 52-column 3, line 3 and column 6, line 27-line 31.)

In D10, a system for controlling dialysis treatment is described. The system includes a cartridge with a soluble concentrate which, after being dissolved, is used to clean the system (see column 2, line 1-line 13.)

D11 discloses a system for preparation of dialysis fluid. The system includes a source of pure water, at least one cartridge with powder to be dissolved for preparation of the fluid and means for conducting the water to the cartridge. A mixing vessel and a re-circulation circuit are used to re-circulate the water through the cartridge until an appropriate fluid concentration is obtained by dissolving the powder in the cartridge partly or entirely (see column 1, line 40-line 58.)

D12 reveals a method and a system for automatic mixing of liquid chemicals following a prescription. The system includes a mixing station with two pumps, valves and sensors used to regulate the mixing of the used chemicals. One pump is used to pump the different chemicals to the mixing station and the other pump is used to pump water. A computer is used to execute the mixing of chemicals following a prescription (see column 1, line 29-line 47; column 2, line 46-line 62; column 4, line 1-line 7 and line 27-line 56 and figures 1 and 2.)

In D13, a system for preparing a medical fluid by mixing concentrates in powder form with water is described. In this system, some powder is dissolved when water is introduced in the powder cartridge. After leaving the cartridge, the liquid solution is diluted to proper concentration by mixing with more water. Different pumps control the flow of liquid from the water reservoir and the powder cartridges. For disinfection, liquid is passed through the system by reversing pumping direction (see page 4, line 18-line 32; page 9, line 24-line 42; the abstract and figure 8.)

D14 describes a water purifier with two reverse osmosis membrane units coupled in series (see claim 1.)

D15 discloses a continuous peritoneal dialysis system in which dialysis fluid is continuously produced (see the abstract and claim 1.)

.../...

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V., 2.

D16 reveals a container for controlled administration of its contents. The container is equipped with a connector with two channels. One channel extends to an upper region of the container (see column 2, line 47-line 60 and figure 2).

D17 describes a penetrating spike with two pathways permitting simultaneous inflow to and outflow from a vial connected to an intravenous administration set (see the abstract and figure 2).

In D18, a drug delivery system is revealed. The system is equipped with a connector with two spikes permitting simultaneous inflow to and outflow from a cartridge containing the drug. One spike extends to the upper portion of the cartridge (see figure 9).

Statement of reasons
Invention 1
The closest prior art is the liquid mixing assembly for peritoneal dialysis disclosed in D1. It reveals the present invention described in claim 1. This claim is therefore not novel.

Using concentrates in powder form, among these glucose and inorganic salts, is well known in the art, see D3, D4 or D5 for example. It is considered obvious for a person skilled in the art to include dry concentrates, sometimes enough to make saturated solutions, in the container according to claim 1. Therefore, claims 2-4 are not considered to involve an inventive step.
The cartridge for production of dialysis fluid described in D2 and the system for controlling a dialysis treatment disclosed in D10 include cleaning solutions. It is considered obvious for a person skilled in the art, even without further knowledge of D2 or D10, to include a chamber with a cleaning agent in the container disclosed in D1, thereby arriving at the invention according to claim 6. What is claimed in claim 7 is also considered obvious for the person skilled in the art, since preparing solutions with different conductivities is well known and often used in dialysis fluid preparation. Thus, claims 6 and 7 are not considered to involve an inventive step.

Accordingly, claim 1 is not novel. Claims 2-4 and 6-7 are novel but not considered to involve an inventive step. The invention fulfils the requirement of industrial applicability.

.../...

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V., 2.

Invention 2

The closest prior art is the liquid mixing assembly for peritoneal dialysis disclosed in D1. The difference between this assembly and the invention according to claim 8 is the special connectors with double lumens, with which the chambers of the invention are equipped. Double lumen connectors permitting simultaneous flow in two directions in production and supply of peritoneal dialysis solution are known through D6. It is considered obvious for a person skilled in the art to apply the connector technique disclosed in D6 on the assembly for liquid mixing in D1 to allow simultaneous inflow and outflow from the different chambers, thereby arriving at the invention according to claims 8, 9 and 11. These claims are therefore not considered to involve an inventive step.

A diffuser that diffuses inflow of liquid in a mixing chamber for dialysis solution is known through D7. Hence, it is considered obvious for a person skilled in the art to provide a diffuser on a fluid channel for inflow into a chamber in the assembly described in D1. The contents of claim 12 are therefore not considered to involve an inventive step.

To add an extra connector with one channel only or to align the connectors along a linear axis, central or not, is considered as obvious constructional details for the person skilled in the art. Thus, claims 10, 13, 14 and 16 are not considered to involve an inventive step.

Accordingly, claims 8-14 and 16 are novel but not considered to involve an inventive step. The requirement of industrial applicability is fulfilled.

Invention 3

The closest prior art is the device for preparation of dialysis fluid described in D8. It reveals the present invention described in claims 68, 70-73, 75-76 and 101-102. These claims are therefore not novel.

The device disclosed in D8 differs from the present invention as described in claims 46-67, 69, 74, 100, and 107-122. For example, it does not contain a steriliser, a heater and a vent. However, it is considered obvious for a person skilled in the art to modify the system in D8 with these details since they represent known components in dialysis fluid production systems, for example the one described in D9. Thereby, the person skilled in the art arrives at the invention as described in claims 46-51, 56-67 and 74 and these claims are

.../...

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V., 2.

therefore not considered to involve an inventive step.
To produce peritoneal dialysis fluid chosen from a group of formulations, the invention includes a controller that controls the mixing as described in claims 53-55 and 107-112. Using a controller and a processor, both included in a computer, for mixing of chemicals following a prescription is known through D12. It is considered obvious for the person skilled in the art to equip the system described in D8 with a controller to be able to make different dialysis fluids for different patients since this is one of the intentions with the system (see especially column 3, line 11-line 16 of D8.) Thus, claims 53-55 and 107-112 are not considered to involve an inventive step.
To include a cell with cleaning agent, to provide a diffuser in a cell with glucose, or to include a water purifier in the system are considered obvious constructional details for the person skilled in the art. These details are known in dialysis systems, see D7, D10 and D14. Claims 52, 69 and 120-122 are therefore not considered to involve an inventive step.
Flushing the liquid path by reversing a pump as described in claim 100 is known through D13. Hence, claim 100 is not considered to involve an inventive step.

Accordingly, claims 68, 70-73, 75-76 and 101-102 are not novel. Claims 46-67, 69, 74, 100, 107-112 and 120-122 are novel but not considered to involve an inventive step. However, claims 113-119 are novel and considered to involve an inventive step. All claims fulfil the requirement of industrial applicability.

Invention 4
The closest prior art is the device for preparation of dialysis fluid described in D8. It reveals the present invention described in claims 77-78, 85, 89-90 and 97. These claims are therefore not novel.

The invention of claims 79-83, 86-88, 91-95 and 98-99 uses a single pump for distribution of the concentrates and the concentrates are diluted after leaving their chambers. This differs from the device disclosed in D8. Also, in the invention the pump is reversed to flush a part of the liquid path. However, the one-pump system is known through D12. Diluting the concentrates, controlling a pump to obtain a desired fluid concentration in a system for preparation of medical fluids and reversing a pump to flush a liquid path is described in D13. It is considered obvious for a person

.../...

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V., 2.

skilled in the art and with prior knowledge of D12 and D13 to modify the device described in D8 with these details, thereby arriving at the invention according to claims 79-83, 86-88, 91-95 and 98-99. These claims are therefore not considered to involve an inventive step.
In claims 84 and 96 calculations of the total amount of concentrate material delivered to a mixing vessel are included. However, using a processor to calculate different characteristics based on sensed parameter values in a system for mixing of different liquids is known through D12. Therefore, it is considered obvious for a person skilled in the art to include these details in the system described in D8 and claims 84 and 96 are not considered to involve an inventive step.

Accordingly, claims 77-78, 85, 89-90 and 97 are not novel. Claims 79-84, 86-88, 91-96 and 98-99 are novel but not considered to involve an inventive step. The requirement of industrial applicability is fulfilled.

Invention 5
Systems for continuous peritoneal dialysis in which dialysis fluid is continuously produced are well known in the art, see D15. The device for preparation of dialysis fluid described in D8 can be used for peritoneal dialysis production and represents the closest prior art. It differs from the invention since it does not provide a processor, a controller, a portable memory and a data input interface. In the system for automatic mixing of liquid chemicals described in D12, a computer with a processor, a memory and an input interface is used to execute the mixing following a prescription. It is considered obvious for a person skilled in the art, with prior knowledge of D12, to computerise the system in D8 to be able to produce different solutions after user input. Thereby he arrives at the invention described in claims 132-140 and these claims are therefore not considered to involve an inventive step.

Accordingly, claims 132-140 are novel and fulfil the requirement of industrial applicability but are not considered to involve an inventive step.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The connection of claim 100 to any of claims 48 to 58 seems erroneous. The pump referred to in the claim can not be found in any of these claims.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/00615

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 1/28, A61M 1/14, A61J 1/06, A61J 3/00, B01D 61/26, B01D 61/28, B01D 61/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M, B01D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95/08299 A1 (TRAVENOL LABORATORIES (ISRAEL) LTD.), 30 March 1995 (30.03.95), page 2, line 33 - page 3, line 1, figure 1, abstract	1
Y	page 2, line 33 - page 3, line 1, figure 1	8-14,16
	--	
X	US 4661246 A (STEPHEN R. ASH), 28 March 1987 (28.03.87), column 2, line 33 - line 42; column 10, line 58 - column 11, line 17, figures 1,2, abstract	1-2,6-7
Y		3-4,75, 111-112
	--	

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 August 2000	04 -09- 2000
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer HÅKAN SANDH/AE Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/00615

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4608043 A (MARK E. LARKIN), 26 August 1986 (26.08.86), column 1, line 5 - line 17, figure 1	1-2,7
Y	EP 0714668 A1 (GAMBRO AB), 5 June 1996 (05.06.96), column 5, line 25 - line 38, abstract	3
Y	JP 08164198 A (CYTEC KK), 25 June 1996 (25.06.96), figure 1, abstract	4
Y	WO 9832478 A1 (BAXTER INTERNATIONAL INC.), 30 July 1998 (30.07.98), page 2, line 32 - page 3, line 14, figures 1-5	8-14,16
Y	DE 3844174 A1 (FRESENIUS AG), 5 July 1990 (05.07.90), figure 1, claim 8	12,69
X	US 5318750 A (JEAN-JACQUES LASCOMBES), 7 June 1994 (07.06.94), column 1, line 25 - column 2, line 15; column 3, line 10 - line 16; column 4, line 26 - line 32	68,70-73, 76-78,85, 89-90,97, 101-102
Y	column 1, line 25 - column 2, line 15; column 3, line 10 - line 16, column 4, line 26 - line 32	46-67,69, 74-75,79-84, 86-88,91-96, 98-100,107-112, 120-122
Y	EP 0428009 A1 (GAMBRO AB), 22 May 1991 (22.05.91), column 2, line 52 - column 3, line 3; column 6, line 27 - line 31	46-67,74, 107-112, 120-22
Y	EP 0458041 A1 (GAMBRO AB), 27 November 1991 (27.11.91), column 2, line 1 - line 13	52

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/00615

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0443324 A1 (GAMBRO AB), 28 August 1991 (28.08.91), column 1, line 40 - line 58	62-65
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE00/00615

Box I **Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 5
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

Claim No. 5 lacks technical features characterising the container it discloses. A meaningful search can consequently not be carried out.

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).:

Box II **Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

See extra sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.: 1-4,6-14,16,46-102, 107-122,132-140

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☒ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE00/00615

I. A container according to claims 1-4 and 6-7.

II. A container according to claims 8-14 and 16.

III. A container according to claims 17-37 and 44-45.

IV. A container according to claims 38-43.

V. A container according to claim 106.

VI. A container for priming powdered glucose according to claim 15.

VII. A method of making a dialysis solution using a plurality of compartments according to claims 46-76, 100-102 and 107-122.

VIII. A method of making an aqueous solution for medical use according to claims 77-99.

IX. A method of making dialysis solution by mixing a plurality of chemicals according to claims 103-105.

X. A method of making a dialysis solution using a water purifier according to claims 123-129, 131 and 141-143.

XI. A method of dialysis treatment where the dialysis solution is sterilized according to claim 130.

XII. A processor for dialysis prescription information according to claims 132-140.

INTERNATIONAL SEARCH REPORT

Information on patent family members

08/05/00

International application No.
PCT/SE 00/00615

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